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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,375	06/02/2005	Giuseppe Sasso	02508.0107	7553

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EXAMINER

SOROUGH, ALI

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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11/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,375

Applicant(s)

SASSO ET AL.

Examiner

Ali Soroush

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 09/06/2007 to the Office Action mailed on 06/11/2007 is acknowledged.

Status of the Claims

Claims 1-10 have been cancelled, claims 11-13, 16, and 20 have been amended. Therefore claims 11-20 are currently pending examination for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 11-18 and 20 under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5200200, published 04/06/1993) **is maintained.**

Applicant Claims

A multiple compartment flexible bag assembly having in one compartment an aqueous sodium bicarbonate solution and in a second compartment an aqueous acid

component, comprising: glucose, acid, sodium, potassium, calcium, magnesium, chloride, and dissolved CO₂.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Veech teaches, "The invention lies in the field of methods for the perpetration of therapeutic aqueous solutions which contain dissolved therein at the time of use unstable metabolites of the type normally present in human blood plasma, and also to the field of filled storable containers useful for the storage of such solutions in unit dose forms." (See column 1, Lines 12-18). "Flexible walled containers incorporating plastics and/or metal foil are currently of growing interest in medical environments and the like. Heretofore, various plastic containers containing integrally a plurality of chambers have been provided for storage of therapeutic materials. Each chamber holds one or a group of separatable components which are admixed into a common solution by chamber wall rupture internally before solution use." (See column 1, Lines 60-67). Veech further teaches, "a method for administration of a redox active parenteral therapeutic solution comprising the steps of (A) dissolving in sterile and substantially pyrogen free water inorganic salts and carbon dioxide which are also both sterile and substantially pyrogen free thereby producing an aqueous solution having the following composition:

<i>Component</i>	Quantity (in mMoles/Liter)
Na ⁺	130-165
K ⁺	0-5
Ca ⁺⁺	0-2.5

Mg ⁺⁺	0-1.5
Cl ⁻	90-120
HCO ₃ ⁻	.5-60
CO ₂	.1-25

..." (See claim 1). Veech teaches more specifically a redox active peritoneal dialysis solution prepared as follows: A master batch solution is prepared containing the components below

Component	Quantity (in mMoles/Liter)
Na ⁺	107.9
K ⁺	4.5
Ca ⁺⁺	1.1
Mg ⁺⁺	0.55
Cl ⁻	102
l-lactate-	10.7
d-betahydroxybutyrate-	3
CO ₂	1.45
Glucose	277
pH	5.0

(See Column 8, example 2). A uniform particulate mixture comprising: particulate NaHCO₃, Na acetoacetate, and particulate Na pyruvate is also prepared. (See column 8, Lines 19-22). The charging procedure is the done according to example 1. (See

column 8, Line 25). Example 1 teaches that sodium pyruvate is mixed with 1 liter of water and charged (filled) into lower compartment of the container and the compartment is sealed. (See column 7, Lines 36-41). Then the master batch solution is charged into the upper compartment of the container and the compartment is sealed. (See column 7, Lines 41-44). When the tabs separating the two chambers are pulled apart the two solutions intermix providing the desired dialysis solution. (See column 8, Lines 27-31). In regards to the partial pressure value of carbon dioxide, the composition of Veech is the same as the composition of the instant invention. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although it is unclear if Example 2 (column 8) taught by Veech uses a solution of sodium bicarbonate, Veech however suggests doing so in Column 8 Lines 25 –26.

Veech teaches that the method by which to charge the two components in the separate compartments should be carried out as described in Example 1 (column 7). In Example 1 Veech teaches a similar master batch solution to be charged into the upper compartment of the container as being prepared in Example 2 and a second particulate component (sodium pyruvate) to be charged into the lower compartment of the container. (See column 7, Lines 20-44). The sodium pyruvate is provided in a one-liter solution of water. (See column 7, Lines 36-38).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to formulate the particulate mixture comprising sodium bicarbonate into an aqueous solution. One would have been motivated to do this because to do so would provide a "ready for conventional intravenous administration" solution (See column 7, Lines 54-55). Further, by providing the particulate mixture comprising sodium bicarbonate in an aqueous solution it would make for a more uniform distribution of the particulates when the two components are mixed for use. Therefore, if a one of ordinary skill in the art wanted to provide a peritoneal solution with increased storage ability and uniform mixing at the time of use one would prepare the two solutions as taught by Veech and place into a multi-compartment bag. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicants Arguments

Applicant argues that Veech does not teach an aqueous sodium bicarbonate component solution but rather teaches a particulate sodium bicarbonate mixture. Applicant therefore argues that Veech neither discloses nor makes obvious every element of independent claim 11. Applicant's arguments have been fully considered and found not to be persuasive.

Although, Veech does not teach that the particulate mixture to be an aqueous solution it would have been obvious to one of ordinary skill in the art at the time of the

instant invention that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container. One would have been motivated to do so because by providing the particulate mixture comprising sodium bicarbonate in an aqueous solution it would make for a more uniform distribution of the particulates when the two components are mixed for use (See Office Action mailed on 06/11/2007, page 7 and 8). For the foregoing reasons the rejection of claims 11-18 and 20 under 35 U.S.C. 103(a) is maintained.

2. The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5200200, published 04/06/1993) in view of Segers et al. (US 5383324, published 01/24/1995) **is maintained.**

Applicant Claims

A multiple compartment flexible bag assembly having in one compartment an aqueous sodium bicarbonate solution and in a second compartment an aqueous acid component, comprising: glucose, acid, sodium, potassium, calcium, magnesium, chloride, and dissolved CO₂. Wherein the multiple component flexible bag is over-wrapped in a flexible gas-impermeable plastic material.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Veech are presented above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Veech lacks the teaching of the multiple compartment flexible bags being over-wrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings in Segers et al.

Segers et al. teaches, "The present invention relates generally to peritoneal dialysis. More specifically, the present invention relates to manufacturing and storing bicarbonate peritoneal dialysis solutions." (See column 1, Lines 6-9). "The device includes an exterior body. The exterior body can be made of any rigid or flexible material that is permeable to water and carbon dioxide." (See column 5, Lines 9-11). Segers et al. further teaches, "The overpouch or second container surrounds both the device and the bicarbonate container. The overpouch is made of any material with low permeability to gas and specifically, carbon dioxide. The low permeability of the overpouch prevents CO₂ from escaping ..." (See column 6, Lines 18-23 and Figure 2).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in art at the time of the invention to use the overpouch of Segers et al. with the invention of Veech. Both patents teach inventions that are to store solutions having carbon dioxide as a component and to be utilized for dialysis purposes. One would be motivated to use the Segers et al.'s overpouch because the plastic containers used by Veech appear to be formed of materials through which carbon dioxide is diffusible. This loss of carbon dioxide leads to the increase in pH of the bicarbonate solution, which leads to the precipitation of calcium carbonate from the solution. The use of the overpouch made of material of low permeability to carbon dioxide would limit the loss of carbon dioxide.

Response to Applicants Arguments

Applicant's arguments and a response to arguments have been addressed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

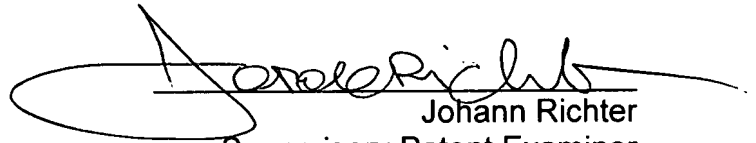
If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616



Johann Richter
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